

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF MARYLAND**

VEIN & WELLNESS GROUP, LLC,

*Plaintiff,*

v.

XAVIER BECERRA, in his official capacity  
as Secretary of the United States Department  
of Health and Human Services,

*Defendant.*

Case No. 1:22-cv-00397-JMC

**PLAINTIFF’S REPLY IN SUPPORT OF ITS  
CROSS-MOTION FOR SUMMARY JUDGMENT**

Plaintiff Vein & Wellness Group’s (“VWG”) motion should be granted. The Secretary violated his own regulations in issuing the denials in this case. Further, the Secretary is barred by collateral estoppel from contesting that the MOCA procedure at issue is a Medicare covered benefit and is “medically reasonable and necessary.” With regard to collateral estoppel, VWG emphasizes that the estoppel is only as between VWG and the Secretary (the Secretary is free to come a different decision as to other parties) and only applies in the absence of “changed circumstances” (which the Secretary has not shown). Having lost the issue against VWG multiple times in the past, the Secretary is not entitled to an infinite number of bites at the apple.<sup>1</sup>

**ARGUMENT**

**A. The Secretary Violated His Own Regulations in Denying VWG’s Claims**

In VWG’s opening papers, VWG showed that, through VWG’s request for an ALJ hearing, the claims in suit had been rejected *solely* on the grounds that the wrong billing code was used or

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<sup>1</sup> *B & B Hardware*, 575 U.S. 138, 147 (2015) (“In short, a losing litigant deserves no rematch after a defeat fairly suffered.”).

that coverage was precluded by LCD L32678/34924. On those two limited bases, it was concluded that the MOCA procedures were not “medically reasonable and necessary.” Accordingly, consistent with 42 C.F.R. §§ 405.1032 and 405.1018, the ALJ was limited to the issues set forth in VWG’s request for an ALJ hearing (i.e., the alleged use of the wrong billing code/the LCDs) and the ALJ could not raise or consider new issues. Thus, the Secretary’s later attempt to justify the denial based on purported new bases (i.e., alleged lack of documentation by the ALJ in some instances and alleged lack of scientific proof of the validity of the MOCA procedure itself by the MAC in all instances) violated applicable regulations. Therefore, it was not in accordance with the law and without observance of the procedure required by law. 5 U.S.C. §§ 706(2)(A)/(D).

Indeed, because the MAC raised the new issue after both the QIC and ALJ hearings, VWG would have been precluded from offering evidence to rebut the improperly raised new issue. Surprise bases for denial of claims is barred by the Secretary’s own regulations.

The Secretary’s opposition begins with a false statement: “It is *undisputed* that the final administrative decision under review is legally correct and supported by substantial evidence.” Opp. at 1 (emphasis in original). Obviously, VWG disputes that the decision is legally correct on multiple bases.

With regard to the violation of the Secretary’s own regulations, the Secretary asserts that, while the ALJ is limited, the body reviewing his work (i.e., the MAC) is not limited and can make its decisions on any basis, including new issues of which the claimant has had no prior notice, and which would require new evidence to rebut/establish. Opp. at 4-5. Thus, as posited by the Secretary, healthcare providers (i.e., VWG) are precluded from offering any evidence not presented to the level below the ALJ (i.e., the QIC). Opp. at 1, n. 1 (*citing* 42 U.S.C. § 1395ff(b)(3)). Simultaneously, the MAC can consider and deny claims on new issues that would

require new evidence to rebut. This would render both the statutory and regulatory scheme contradictory and nonsensical, violating fundamental standards of statutory and regulatory construction. *See* Scalia & Garner, *READING LAW: THE INTERPRETATION OF LEGAL TEXTS* (2012) § 27 (“The provisions of a text should be interpreted in a way that renders them compatible, not contradictory.”).

If the claimant was limited to evidence submitted to the QIC, but the MAC was free to consider new issues requiring new and different evidence, then the entire scheme would devolve to a game of trickery. Clearly, that is not what was intended. First, having notice of the basis of denials, providers are required to come forward with the evidence they intend to rely on and present it to the QIC. If they are dissatisfied with QIC’s decision, a provider can appeal to an ALJ but cannot come forward with new evidence that the QIC did not have an opportunity to consider. Further, the ALJ’s consideration is limited to those issues the provider sets forth in his request for ALJ review. Obviously, a ALJ cannot make an error of law by failing to consider new issues and MAC review is likewise limited to the issues identified in the request for ALJ review, of which the claimant had notice and opportunity to submit evidence. The Secretary’s position in this regard is without merit.

Next, the Secretary contends that VWG had notice of the issue of whether the MOCA procedure was “medically reasonable and necessary.” *Opp.* at 5-6. In this regard, the Secretary does not dispute that VWG was only provided notice that “medical reasonableness and necessity” was denied on the grounds that the wrong billing code was used/coverage was barred by an LCD and not some other basis.<sup>2</sup> Given that those were the only bases disclosed, those were the only

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<sup>2</sup> In this regard, VWG notes that there are at least 65 different bases on which a claim could be denied as “medically unreasonable and necessary.” *See* <https://www.cms.gov/files/document/generic-part-b-reason-codes-and-statements.pdf>

issues VWG was provided notice of and an opportunity to submit evidence at the QIC stage. Accordingly, when the ALJ (in some instances) and the MAC (in all instances) premised denials on new issues, the ALJ and the MAC violated the Secretary's own regulations. Thus, the denials should be reversed.

**B. The Secretary is Collaterally Estopped from Denying the Plaintiff's Claims.**

As set forth in VWG's opening papers, there is a presumption that collateral estoppel applies when an agency is acting in a judicial capacity (as the Secretary was here) and all the elements of collateral estoppel are present. The Secretary's opposition fails to sustain the Secretary's burden of showing that Congress intended to abrogate the common law of collateral estoppel. With regard to the elements of collateral estoppel, VWG has shown that they are present, and the Secretary's opposition fails to show otherwise. Thus, the Secretary is barred by collateral estoppel from rejecting VWG's claims.

**1. Collateral Estoppel Applies to Medicare Cases**

As VWG set forth in its opening papers, when a government agency is acting in a judicial capacity, it is presumed that the common law doctrine of collateral estoppel applies. *See Astoria Federal Savings & Loan Ass'n v. Solimino*, 501 U.S. 104, 10708 (1991); *B & B Hardware*, 575 U.S. 138, 148-151 (2015) (confirming presumption that administrative decisions are subject to issue preclusion).<sup>3</sup> A party asserting that collateral estoppel does not apply bears the burden of

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<sup>3</sup> *See also, e.g., Fairmont Aluminum Co. v. C.I.R.*, 222 F2d 622, 627 (4<sup>th</sup> Cir. 1955):

It is perfectly clear, however, that whether the Tax Court be regarded as a court or as an administrative agency, it is exercising judicial functions in hearing tax cases of this character; and, when exercising judicial functions, as distinguished from administrative functions, it is bound to apply such fundamental judicial doctrines as *res judicata* and estoppel.

*Id.*

establishing that the presumption has been overcome. *See Green v. Bock Laundry Machine Co.*, 490 U.S. 504, 521 (1989) (“has the burden of showing that the legislature intended such a change.”).<sup>4</sup> To overcome the presumption of the common law, a party must demonstrate that Congress clearly evidenced an intent to do so. *Astoria*, 501 U.S. at 109-110; *U.S. v. Texas*, 507 U.S. 529, 535 (1993) (“an expression of legislative intent to supplant”); *Green*, 490 U.S. at 521 (must show “legislature intended such a change”). Moreover, to overcome the presumption, a statute must “speak directly” to the common law issue. *See Texas*, 507 U.S. at 534. Statutes which are compatible with the pre-existing practice of the common law do not overcome the presumption. *See BFP v. Resolution Trust Corp.*, 511 U.S. 531, 543 (1994) (“a phrase entirely compatible with pre-existing practice”).

In the present case, the Secretary does not dispute that he was/is acting in a judicial capacity when the ALJs and the MAC considered and ruled on both the prior cases and the current case. Thus, the issue reduces to the question of whether the Secretary has carried his burden of rebutting the presumption of the common law by pointing to statutes passed by *Congress* that evidence *Congress*’ intent to abrogate the common law. The Secretary’s alleged showing appears at pages 7-17 of the Secretary’s opposition. The Secretary did not carry his burden.

**a. The Secretary’s Regulations Are Not Statutes  
And Do Not Reflect Congress’ Intent**

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<sup>4</sup> In a footnote, the Secretary erroneously asserts that VWG bears the burden with regard to collateral estoppel and attempts to distinguish *Green*. Opp. at 18, n. 12. As set forth in *Astoria*, it was the plaintiff that bore the burden of overcoming the presumption and showing that collateral estoppel did not apply because of the structure of the ADEA. Consistent with the presumption, the common law is the “settled law.” Thus, exactly as set forth in *Green*, the party asserting a change in the “settled law,” here the Secretary, bears the burden of showing that the “legislature intended such a change.” Once it is determined that collateral estoppel may apply to the type of case generally, the burden of proving that the elements of collateral estoppel are present in an individual case is on the party asserting collateral estoppel.

The Secretary argues that his own regulations bar collateral estoppel. Opp. at 10-12. Of course, regulations are *not* statutes passed by Congress and regulations do not reflect *Congress'* intent. To carry his burden, the Secretary must show that the “legislature [*i.e.*, Congress] intended such a change.” *See Astoria, Texas, Green*. Thus, the Secretary cannot carry his burden by relying on his own regulations. Opp. at 12 (“Medicare regulations clearly state ...”).

For the same reason, the Secretary’s citation to the RESTATEMENT (SECOND) OF JUDGMENTS (Opp. at 12) is inapposite. The quoted section (Section 83, Para. 4) indicates that collateral estoppel may not apply if it would be “incompatible with a legislative policy.” The Secretary is not the legislature. That is Congress. Thus, the Secretary’s regulations add nothing to the showing the Secretary must make.

**b. *De Novo* Review Is Fully Compatible With Collateral Estoppel**

With regard to statutes passed by Congress, the only one pointed to by the Secretary is 42 U.S.C. § 1395ff(d)(2)(B). Opp. at 11. That provision states:

DAB hearing procedure

In reviewing a decision on a hearing under this paragraph [*i.e.*, an ALJ decision], the Departmental Appeals Board shall review the case *de novo*.

This merely describes the common situation where appellate review is *de novo*. That only means that the matter is reviewed with no deference to the conclusions of the tribunal being reviewed. It does not mean that prior, final decisions cannot impact how a subsequent proceeding is reviewed or that the presence of *de novo* review is somehow incompatible with collateral estoppel. Indeed, in *B & B Hardware*, the Supreme Court addressed this very scenario. There, it was argued that decisions in Trademark Trial and Appeals Board (TTAB) proceedings should not give rise to preclusive effect because they are subject to *de novo* review in a district court. Disagreeing, the Supreme Court held:

Ordinary preclusion law teaches that if a party to a court proceeding does not challenge an adverse decision that decision can have preclusive effect in other cases, even if it would have been reviewed *de novo*.

575 U.S. at 151-2.

Moreover, multiple statutes contain *de novo* review provisions, yet collateral estoppel can still apply in those proceedings where there is an earlier litigation. For example, 8 U.S.C. §1421(c) provides for district court “*de novo* review” of naturalization decisions. As cogently explained by one Court:

[T]he *de novo* review requirement of § 1421(c) means only that the court should not defer to USCIS with respect to findings and conclusions regarding the naturalization proceeding being reviewed and that it does not mean that other decisions by courts or agencies cannot have preclusive effect.

*Ahmad v. Johnson*, 2017 WL 6945395, at \*9-10 (N.D. Cal. Oct. 10, 2017) (emphasis in original). Likewise, 8 U.S.C. §1503 (proceedings to determine citizenship) has been interpreted to provide for *de novo* review by district courts. Nevertheless, collateral estoppel has been applied to bar re-litigation of underlying facts determined in an earlier proceeding. *See Ortega v. Holder*, 2010 WL 4625580 (N.D. Ill. Nov. 5, 2010) (Attorney General collaterally estopped from denying facts which supported citizenship determined in earlier removal proceedings).

Indeed, appeals courts review motions granting summary judgment *de novo*, as well as District Court rulings on issue preclusion. *See, e.g., Cowgill v. First Data Tech., Inc.*, 2022 WL 2901043 (4<sup>th</sup> Cir. July 22, 2022) (“This Court reviews a district court’s grant of summary judgment *de novo* ...”); *Hatley v. Watts*, 917 F.3d 770, 777 (4<sup>th</sup> Cir. 2019) (“We review the application of issue preclusion *de novo*.”). Thus, if *de novo* review were inconsistent with collateral estoppel, collateral estoppel could never apply and that is, obviously, preposterous.

Applying the Supreme Court’s standards, §1395ff(d)(2)(B)’s “*de novo* review” does not “speak directly” to the issue of collateral estoppel (*Texas*, 507 U.S. at 534) or reflect that a

“statutory purpose to the contrary is evident” (*Astoria*, 501 U.S. at 108), and *de novo* review is fully compatible with the pre-existing law of collateral estoppel (*BFP*, 511 U.S. at 543). The Secretary did not carry his burden.

**c. Collateral Estoppel Is Not Contrary to the Appropriations Clause**

The Secretary contends that he cannot be collaterally estopped because doing so would violate the Appropriations Clause of the Constitution. Opp. at 16-17. In doing so, the Secretary relies on three cases all of which follow the same fact pattern: someone with the government (not acting in a judicial capacity) erroneously tells a private party that the government will pay for something when there is no statute authorizing the payment. Subsequently, the government recants the prior representation, and the private party asserts that the government is *equitably estopped* from refusing to pay. That is the fact pattern of *Office of Personnel Management v. Richmond*, 496 U.S. 414 (1990) (“erroneous oral and written advice given by a Government employee to a benefits claimant may give rise to estoppel against the Government and so entitle the claimant to a monetary payment not otherwise permitted by law”); *Monogahela Valley Hospital, Inc. v. Sullivan*, 945 F.2d 576 (3<sup>rd</sup> Cir. 1991) (equitable estoppel asserted based on prior position asserted by contractor); and *Downtown Medical Center/Comprehensive Health Care Clinic v. Bowen*, 944 F.2d 756, 771 (10<sup>th</sup> Cir. 1991) (“CHC was advised by its Blue Cross Medicare Prover relations Representative ...”).

Obviously, the difference between those cases and this case include: 1) in those cases there was no statutory authority for the alleged expenditure of funds, whereas that there was/is such authority was the very thing decided in the prior cases involving VWG; and 2) what was asserted there was equitable estoppel, whereas here collateral estoppel is asserted. Thus, these cases are simply inapposite to the issues before this Court. Again, at base, the Secretary bears the burden

of showing that statutes passed by Congress evidence *Congress'* intent to abrogate the common law of collateral estoppel and nothing the Secretary has pointed to does that.

Indeed, at least with regard to whether mutual collateral estoppel can apply against the government in a matter related to benefits, this case is very similar to *U.S. v. Moser*, 266 U.S. 236 (1924). There, Captain Moser contended that he was entitled to enhanced retirement benefits stemming from his time as a student at the Naval Academy during the Civil War.<sup>5</sup> When the government refused to provide the enhanced benefits (which apparently came in tranches), Moser sued in the Court of Claims, won, and the government did not appeal. This happened two more times and the Court of Claims found for Moser again, but these times based on *res judicata* (*i.e.*, collateral estoppel). Again, the government did not appeal. In the fourth suit, the Court of Claims again found in Moser's favor on *res judicata* grounds but this time the government appealed contending that it could not be bound by *res judicata* (*i.e.*, collateral estoppel). The Supreme Court disagreed and held that the government was, in fact, estopped and Moser entitled to the enhanced retirement benefits.<sup>6</sup>

The Secretary has not shown that collateral estoppel is contrary to the Appropriations Clause.

#### **d. The Secretary's Comments Regarding *Astoria***

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<sup>5</sup> Under a statute passed by Congress, any officer of the Navy who "served during the Civil War", upon retirement, was entitled the next highest rank and three-fourths of the sea pay of that rank. Thus, if Captain Moser "served during the Civil War", he would retire with the rank and three-fourths the sea pay of a Rear Admiral, rather than a Captain. Thus, the question was whether being a student at the Naval Academy during the Civil War constituted "service during the Civil War."

<sup>6</sup> Lest this Court think that *Moser* is moribund/has fallen into disuse, VWG notes that *Moser* was cited in *U.S. v. Mendoza*, 464 U.S. 154 (1984), where the Supreme Court held that non-mutual collateral estoppel did not apply against the government (*i.e.*, because of the government's unique litigation position, the loosening of the collateral estoppel mutuality requirement of *Parklane Hosiery Co. v. Shore*, 439 U.S. 322 (1979) did not apply to the government) but that traditional mutual collateral estoppel did. *Mendoza*, 464 U.S. at 163-4.

The Secretary's comments about *Astoria* (Opp. at 8-9) seem to misunderstand the case. There, at issue was the federal Age Discrimination in Employment Act (ADEA). Pursuant to the ADEA statute, *as a prerequisite to filing suit in federal court in the same controversy*, the plaintiff had to file suit in State court. Only after filing the State action could the plaintiff file a federal suit. In *Astoria*, the plaintiff complied and first filed a State court action, where he lost. Then, he filed a federal action on the same controversy. In the federal action, the defendant asserted collateral estoppel based on the State action and the federal action was dismissed. On review at the Supreme Court, the Court first held that agency action could give rise to collateral estoppel. Then, the Court did the analysis VWG asserts is required. That is, the Court looked to the statutes passed by Congress to determine whether those statutes evidenced Congress' intent to abrogate collateral estoppel in these cases. In the case of the ADEA, the Supreme Court held that the statute did show Congress' intent because, were collateral estoppel to apply based on the required State suit in the same controversy, the federal suit would be superfluous and, obviously, Congress could not have intended that. Here, that same analysis does not identify any statute passed by Congress which evidences the intent to abrogate collateral estoppel. Moreover, as the party asserting that the common law of collateral estoppel has been abrogated, the Secretary bears the burden of proving the same through statutes passed by Congress, and the Secretary has not met that burden.

**e. The Secretary's Other Arguments Lack Merit**

On pages 12-14, the Secretary presents the broad claim that he can decide whether collateral estoppel applies. Opp. at 14 ("Accordingly, it is within the Secretary's discretion *not* to be bound by ALJ rulings.") (emphasis in original). There is no merit to such a claim and, even if Congress had attempted to delegate such power, it would be unconstitutional.

The Supreme Court has explained that the “common law” (including collateral estoppel) “comprises the body of those principles and rules of action relating to the government and security of persons and property, which derive their authority solely from usages and customs of immemorial antiquity.” *Western Union Telegraph Co. v. Call Publishing Co.*, 181 U.S. 92, 102 (1901). As explained by the Supreme Court, only Congress has the power to abrogate the common law. To the extent that the Secretary’s contends that Congress delegated to a non-elected appointee the power to decide whether “the usages and customs of immemorial antiquity” apply to American citizens, that would be unconstitutional. The Constitution vests all legislative powers in Congress - U.S. Const. art. I, §1 - which the Supreme Court has read to mean that “Congress may not constitutionally delegate its legislative power to another branch of Government.” *Touby v. U.S.*, 500 U.S. 160, 165 (1991). Thus, any contention that Congress has delegated its legislative power to abrogate the common law to the Secretary is barred by the Constitution.

On pages 7-8, the Secretary offers comments regarding *Prosser* and collateral estoppel, which the Secretary cites as: *Prosser v. Azar*, 20-C-194, 2020 WL 3642315, at \*5 (E.D. Wisc. July 6, 2020) *aff’d on other grounds*, *Prosser v. Becerra*, 2 F.4<sup>th</sup> 708 (7<sup>th</sup> Cir. 2021). Opp. at 7. That is a misrepresentation. In *Prosser*, the District Court first ruled that collateral estoppel did not apply before deciding that it lacked jurisdiction to even consider the case. *See Prosser v. Azar*, 2020 WL 6266040 (E.D. Wisc. October 21, 2020). Thus, by operation of law, the District Court’s opinion concerning collateral estoppel was vacated and it was the opinion regarding jurisdiction that was affirmed. Citing vacated decisions without disclosing the same does not bolster the Secretary’s position. That aside, in the vacated, unreviewed *Prosser* opinion, the district court began with the correct analysis before going astray. The District Court found that there was no “statutory language speaking directly to the doctrine of collateral estoppel.” *Id.* at \*5. That should

have been the end of inquiry because that is the very thing that is required to overcome the presumption of the common law (*i.e.*, collateral estoppel). *Texas*, 507 U.S. at 534. The District Court went astray when it then examined the Secretary's regulations to see if they allowed collateral estoppel. Again, only Congress has the power to abrogate the common law and Congress cannot Constitutionally delegate that power to another branch. While the District Court there made other errors, the failure to follow the dictates of the Supreme Court in determining whether the Congress has abrogated the common law was the initial failure.

On pages 9-10, the Secretary attempts to distinguish a raft of cases in which collateral estoppel has been applied based on agency determinations (both against private parties and against the government). The Secretary attempts to distinguish some cases (*e.g.*, *Continental Can v. Marshall*, 603 F.2d 590 (7<sup>th</sup> Cir. 1979)) on the grounds that they came before *Astoria*. While *Astoria* is the most recent case and has a nice quote, the proposition that collateral estoppel may be based on agency action is long-standing. Indeed, *Continental Can* cites some cases so holding (*id.* at 594), including *U.S. v. Utah Construction Mining Corp.*, 384 U.S. 394 (1966), where the Supreme Court stated (repeated almost verbatim in *Astoria*):

When an administrative agency is acting in a judicial capacity and resolved disputed issues of fact properly before it which the parties had an adequate opportunity to litigate, the courts have not heisted to apply *res judicata* [*i.e.*, collateral estoppel] to enforce repose.

*Id.* at 422. *Utah Construction* itself cites an even older case where collateral estoppel was applied based on a prior agency finding. In *Sunshine Anthracite Coal Co. v. Adkins*, 310 U.S. 381 (1940), at issue was whether certain coal was subject to taxes/a statute and the power of the National Bituminous Coal Commission. The NBCC held that it had the power to decide whether coal at issue was “bituminous” and, therefore, within the provisions of the statute related to taxes. Then, the NBCC found that the coal was “bituminous.” In a suit by a related entity to stop collection of

the taxes, etc., the government argued that re-litigation of the power of the NBCC was barred by collateral estoppel. The Supreme Court addressed the issue, holding:

A judgement is *res judicata* in a second action upon the same claims between the same parties or those in privity with them. There is privity between officers of the same government so that a judgment in a suit between a party and a representative of the United States is *res judicata* in relitigation of the same issue between that party and another officer of the government.

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But here the authority of the [NBCC] is clear. There can be no question that it was authorized to make the determination of the status of appellant's coal under the Act. It represented the United States in that determination and the delegation of that power to the [NBCC] was valid, as we have said. *That suit therefore bound the United States, as well as the appellant.* Where a suit binds the United States, it binds its subordinate officials.

*Id.* at 403 (emphasis added, cleaned up). These cases answer the Secretary's charge that the government is not bound by collateral estoppel generally or bound by agency decisions.

The Secretary's general claim that collateral estoppel is not presumed to apply (Opp. at 9-10) flies in the face of all the cases by the Supreme Court.

The Secretary's reliance on *Porzecanski v. Azar*, 942 F.3d 472 (D.C. Cir. 2019) and *Almy v. Sebelius*, 679 F.3d 297 (4<sup>th</sup> Cir. 2012) is unavailing. Opp. at 11-12. In *Porzecanski*, the plaintiff sought an injunction barring *future* rejection of his claims. 942 F.3d at 477 ("will not deny Medicare Part B coverage for *future* IVIG treatments") (cleaned up). An injunction requiring approval of claims not yet submitted is, of course, vastly different than asserting mutual collateral estoppel on claims already submitted. Even where collateral estoppel applies, collateral estoppel does not support future injunctions because there may be "changed circumstances." *See, e.g., Montana v. U.S.*, 440 U.S. 147, 159 (1979) ("changes in facts essential to a judgment will render collateral estoppel inapplicable"). Thus, *Porzecanski* adds nothing, although the section quoted by the Secretary actually makes VWG's point about mutual collateral estoppel. *Id.* ("Because the

review generally only binds the parties ...”). VWG and the Secretary were parties to the prior proceedings and, as VWG asserts, the Secretary is bound by the results there.

The Secretary’s effort to rely on *Almy* is misplaced. First, *Almy* does not concern mutual collateral estoppel and instead relates to review under the “arbitrary and capricious” standard. 679 F.3d 310 (“BioniCare last argues that the Secretary’s decisions were arbitrary and capricious ...”). Second, in part, BioniCare attempted to rely on decisions below the ALJ level, where the Secretary is not acting in a judicial capacity. *Id.* (“Because some ... contractors have covered the device and some have not ...”). Third, BioniCare apparently sought to rely on decisions in cases that did not involve BioniCare and VWG notes that the Fourth Circuit was careful to focus on who may be bound by a decision. *Id.* (“Nowhere does any policy or regulation suggest that the MAC owes any defense at all to – much less is bound by – decisions of lower reviewing bodies addressing different disputes *between different parties* merely because they pertain the to the same device.”) (emphasis added). By contrast, the present case is the same dispute between the same parties pertaining to the same service/device. This is the archetypal situation in which collateral estoppel applies.

The Secretary’s contention that applying collateral estoppel would interfere with his discretion (Opp. at 12-13) is merely the claim that the Secretary can decide whether the common law applies. As discussed above, that is a power that the Secretary lacks. While the Secretary has discretion to decide whether items may be covered categorically or to litigate the issue in individual cases (subject to the statutes), however it is litigated, the Secretary is bound by collateral estoppel just as any party would be.

The Secretary has not carried his burden of showing that *statutes* passed by *Congress* evidence *Congress’* intent to abrogate the common law of collateral estoppel. Because the

secretary failed to sustain his burden and rebut the presumption of collateral estoppel, collateral estoppel applies to Medicare cases.

## **2. The Elements of Collateral Estoppel Are Present in This Case**

As VWG showed in its opening papers, all the elements of collateral estoppel are present in this case. Further, VWG notes that this is the fourth litigation of Medicare coverage by VWG and avoiding repeated litigation of identical issues (and the resulting waste and burden on the parties and the courts) is one of the purposes of collateral estoppel.<sup>7</sup>

### **a) The Issue Or Fact Is Identical To the One Previously Litigated**

As discussed in VWG's opening papers, the prior decisions determined that MOCA was a Medicare covered benefit. Likewise at issue in every Medicare case is whether the claim or service is a Medicare covered benefit. Pursuant to the statutes, only items that are "medically reasonable and necessary" are covered by Medicare. *See* 42 U.S.C. § 1395y(a)(1)(A). Thus, anytime it is decided that a claim is covered, it has necessarily been determined that the service/item is medically reasonable and necessary. As shown in Exhibits A, B, and C, the MOCA procedure was determined to be a Medicare covered benefit (and, therefore, "medically reasonable and necessary") in the prior decisions.

The Secretary does not dispute that the prior decisions determined that MOCA is a Medicare covered benefit or that a finding that a device/service was "medically reasonable and

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<sup>7</sup> While the Secretary does not contest the issue, VWG notes that, because of the manner in which it may arise, judicial notice of other proceedings/decisions giving rise to collateral estoppel is common. *See, e.g., Brooks v. Arthur*, 626 F.3d 194, 200 (4<sup>th</sup> Cir. 2010); *Ashe v. PNC Financial Services, Group, Inc.*, 652 Fed.App'x 155 (4<sup>th</sup> Cir. 2016); *See, e.g., Lobo v. Celebrity Cruises, Inc.*, 704 F.3d 882, 892-93 (11<sup>th</sup> Cir. 2013) (judicial notice of entry of judgment in related proceeding supporting collateral estoppel); *Coney v. Smith*, 738 F.2d 1199, 1200 (11<sup>th</sup> Cir. 1984) (judicial notice of state court proceedings supporting collateral estoppel); *Ross v. Meyer*, 741 Fed.Appx. 56, 59 (3<sup>rd</sup> Cir. 2018) (judicial notice of decisions in parallel proceedings).

necessary” is a prerequisite to finding that a device/service is covered under the statute. Nevertheless, the Secretary contends that the issue of whether MOCA was “medically reasonable and necessary” was not litigated in the prior cases. Opp. at 18-19.

Given the Secretary’s failure to dispute that the issue of Medicare coverage of the MOCA procedure was decided in the prior cases and that that is the ultimate issue/very thing also decided in the present case, the issues are identical.

As to the sub-issue of whether the MOCA procedure is “medically reasonable and necessary”, because a determination of that issue is a prerequisite to a determination that something is covered, that issue was necessarily decided in the prior cases. That is, the ALJs in those cases could not have decided that MOCA was a Medicare covered benefit without also deciding that MOCA was “medically reasonable and necessary.” *See, e.g., Samson v. Hecht*, 64 F.3d 659 at \*2-3 (4<sup>th</sup> Cir. 1995) (cited for illustrative purposes) (issue decided in prior case when it was a necessary predicate to conclusion, collateral estoppel applied).

Thus, the issue of whether MOCA is a Medicare covered benefit/is “medically reasonable and necessary,” is identical in all the cases.

**b) The Issue or Fact Was Actually Resolved in the Prior Proceeding**

The Secretary’s dispute regarding this element is limited to the Secretary’s contention that whether the MOCA procedure is “medically reasonable and necessary” was not litigated in the prior decisions. Accordingly, for the same reason that position is wrong, it is likewise wrong for this element and the issue was resolved in the prior proceeding.

**c) The Issue or Fact Was Critical and Necessary to the Judgment in the Prior Proceeding**

The Secretary did not respond on this element. Obviously, given that Medicare coverage of the MOCA procedure was the very thing being disputed and sought in the prior proceedings, a

determination that the MOCA procedure is a Medicare covered benefit was critical and necessary to the judgment. Likewise, because coverage is dependent on a service/device being “medically reasonable and necessary” (42 U.S.C. § 1395y(a)(1)(A)), resolution of that fact/issue in VWG’s favor was a critical and necessary to the judgment in the prior decisions. Thus, this element is conceded.

**d) The Judgment in the Prior Proceeding Is Final and Valid**

The Secretary did not dispute this element and it is conceded.

**e) The Secretary Had a Full and Fair Opportunity to Litigate in the Prior Proceedings**

The Secretary’s response to this element appears on pages 20-22 of the opposition. The Secretary fails to challenge this element: that is, the Secretary does not contest that he could have participated in the proceedings before the ALJs, could have called witnesses, presented arguments, etc. Thus, the element is conceded.<sup>8</sup>

What the Secretary does argue is that there are various reasons why he chose not to take advantage of his opportunity to contest the issue. One such reason is that the Secretary contends that it is “impractical” for him to participate in the proceedings. Opp. at 20-21. This is so, the Secretary contends, because there are “over 400,000 Medicare claims appeal filed each year at the ALJ level.” In making this representation, the Secretary cites a publication from 2016.

Thus, rather than anything to do with VWG’s case specifically, the Secretary asserts that the common law (i.e., collateral estoppel) should be abrogated based on asserted administrative convenience rather than because of Congressional statute. As the Supreme Court noted in *Niz-*

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<sup>8</sup> The Secretary’s contentions about proceedings below the ALJ level are irrelevant. Below the ALJ level, the Secretary is not acting in a judicial capacity. At the ALJ and MAC level, the Secretary is acting in a judicial capacity. Collateral estoppel may only be based on decisions issued when an agency is acting in a judicial capacity.

*Chavez v. Garland*, 141 S.Ct. 1474, 1485 (2021), pleas of administrative convenience are “never” proper bases for departing from a statute’s text or, here, the common law.

Further, the Secretary’s representation is demonstrably false and misleading. In 2012 and 2013, the Secretary retroactively denied hundreds of thousands of claims related to hospital stays. That led to a commensurate number of appeals by the hospitals and tremendous delay in resolving them by the Secretary. In a lawsuit challenging the backlog of ALJ appeals starting in 2013, *American Hospital Assoc. v. Azar*, 2018 WL 5723141 at \*4 (D.D.C. Nov. 1, 2018)), the Court issued a *writ of mandamus* requiring the Secretary, *inter alia*, to entirely eliminate the backlog by the end of FY2022 and also requiring the Secretary to submit quarterly status reports on his progress. *Id.* The most recent report from June 27, 2022, is attached as Exhibit 1 and indicates that in FY21, ~31,000 appeals (of all types)<sup>9</sup> were filed, ~136,000 appeals were resolved, and the backlog currently stands at ~37,000 appeals. Thus, the actual numbers are less than 10% of the numbers provided by the Secretary. Regardless, whatever volume challenges there may be, they are momentary, while collateral estoppel derives from the “ancient unwritten law of England.” *Western Union Telegraph Co. v. Call Publishing Co.*, 181 U.S. 92, 102 (1901).

The Secretary’s claims about his ability to appeal are also specious. Opp. at 21. As VWG noted in its opening papers, the Secretary’s own regulations provide two routes for the Secretary to appeal an ALJ decision, depending on whether the Secretary chose to attend the ALJ hearing. See 42 C.F.R. §§ 405.1100-1140. Indeed, the present case is illustrative. The Secretary chose not to attend the ALJ hearings in this case. Nevertheless, dissatisfied with the decision of his own ALJ, the Secretary appealed using the “own motion” review procedure 42. C.F.R. § 405.1110. See, e.g., AR14; AR23-44. Thus, the Secretary’s contentions about his ability to appeal are simply

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<sup>9</sup> That is, the number includes Social Security appeals, etc. and it not limited to Medicare claims.

incorrect. Moreover, if the Secretary chooses to adopt procedures that limit his participation in the litigation, those are voluntary and have no effect on whether collateral estoppel applies.

The Secretary's contention that he was not a party to the proceedings conducted in his name by his own ALJs lacks merit. Opp. at 21-22. Indeed, the Secretary's contention is belied by the caption in this case – "VWG v. Xavier Becerra, in his official capacity as Secretary of the Department of Health and Human Services." Decisions issued by ALJs and the MAC are decisions of the Secretary and the Secretary is always a party to the proceedings he conducts. *See also, e.g., Sunshine*, 310 U.S. at 403.

While the Secretary suggests he lacked an incentive to litigate (Opp. at 23), he makes no effort to demonstrate its applicability to this case. As the Supreme Court explained in *B & B Hardware*, 575 U.S. at 159, collateral estoppel may be "inapt if the amount in controversy in the first action was so small in relation to the amount in controversy in the second that preclusion would be plainly unfair." Likewise, in *Parklane Hosiery Co., Inc. v. Shore*, 439 U.S. 322, 330 (1979), the Supreme Court indicated that if the amount in the first action is so small, a party may have little incentive to litigate "particularly if future suits are not foreseeable."

Here, the Secretary makes no effort to demonstrate that the amounts in controversy in the prior cases were so small in relation to the present case that collateral estoppel would be unfair. Likewise, the Secretary makes no effort to demonstrate that future claims by VWG for MOCA procedures were unforeseeable. Thus, the Secretary has entirely failed to make the showing required for the "lack of incentive to litigate" exception to apply.

What the Secretary does contend is that, just generally speaking, he believes that more fully participating in ALJ/MAC cases "would be an inefficient use of resources better put towards the

Medicare program.”<sup>10</sup> As a result of his own choices, the Secretary contends that he should be exempt from the common law of collateral estoppel, *i.e.*, “the usages and customs of immemorial antiquity.” *Western Union*, 181 U.S. at 102. Whether the Secretary should be exempt from the common law of collateral estoppel is a decision for Congress, not the something subject to the Secretary’s convenience.

Again, the Secretary failed to make the required showing for the exemption. As all the elements of collateral estoppel are present, VWG is entitled to judgment as a matter of law.

### **CONCLUSION**

For the reasons set forth above, the Court grant VWG’s motion for summary judgment and find that the Secretary is collaterally estopped from denying coverage of the claims at issue in this case and that the Secretary’s denials issued in violation of the applicable laws/regulations. Pursuant to 42 U.S.C. § 405(g) (fourth sentence), the Court should remand this matter to the Secretary with instructions to cover all the claims at issue.

Dated: August 4, 2022

Respectfully submitted,

/s/Daniel Z. Herbst  
Daniel Z. Herbst (Bar No. 17510)  
REED SMITH LLP  
1301 K Street, NW  
Suite 100-East Tower  
Washington, DC 20005  
(202) 414-9232  
dherbst@reedsmith.com

*Counsel for Plaintiff*

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<sup>10</sup> At the same time, the Secretary has no problem if claimants are forced to expend their resources in the Sisyphean task of repeatedly litigating Medicare coverage. Avoiding the unfairness of this situation is one reason collateral estoppel exists in the first place.

**CERTIFICATE OF SERVICE**

I hereby certify that on August 4, 2022, a true and correct copy of the Plaintiff's Reply in Support of its Cross Motion for Summary Judgment was filed via the Court's CM/ECF system and served upon all attorneys of record.

/s/Daniel Z. Herbst  
Daniel Z. Herbst (Bar No. 17510)